

ST



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,380	05/26/2000	Bradford W. Gibson	UCSFP001/1584.002	1111

27476 7590 03/24/2006

Chiron Corporation
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097

EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/580,380

Applicant(s)

GIBSON ET AL.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,8-14,21-24 and 75-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,8-14,21-23 and 75-82 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 0306.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Art Unit: 1631

DETAILED ACTION

Applicants' arguments, filed 14 December 2005, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1, 5, 8-14, 21-24, and 75-82 are currently pending. Claims 2-4, 6, 7, 15-20, and 25-74 have been cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1631

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 8-14, 21-23, and 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lacroix et al. (Biochemistry (1997) Vol. 36, pages 6270-6282), in view of Mitra et al. (Journal of the American Chemical Society (1979) Vol. 101, pages 3097-3110), in further view of Havel et al. (Biopolymers (1979) Vol. 18, pages 73-81), for the reasons set forth in the previous Office Action.

Response to Applicant's Arguments

1. Applicant argues that the present invention employs a combination of the following steps to determine the tertiary structure of a protein:

A. providing a set of candidate three-dimensional conformations for the protein's primary sequence and

B. applying physical distant constraint information associated with the cross-linking for the identified cross-link fragments to the candidate three-dimensional conformations to rank said three-dimensional conformations and selecting one or more of said three-dimensional conformations based on the rankings.

Applicant argues that none of the cited references, alone or in combination, teach or suggest the combination of A. and B.

Art Unit: 1631

Applicant states that “what these references do not suggest is use of cross-linking and subsequent analysis as claimed to determine a tertiary structure of the polypeptide”. Applicant states that Lacroix does not propose a set of three-dimensional conformations.

This is not persuasive. Lacroix does teach a set of three-dimensional structures, as set forth in the previous Office Action. It was stated that “Lacroix discloses that the homology modeling is similar to that of Rossi. Rossi et al disclose a threading technique by where a set of homologous three-dimensional structures is used as a reference template, sequence of proteins are aligned and the candidate structure is identified by comparing said structure to the reference set (previous Office Action page 4)”.

2. Applicant states that neither Mitra nor Havel suggest the claimed features that are lacking in Lacroix. Applicant states that combining the cross-linking reagents taught in Mitra with the method of protein structure determination of Lacroix would not result in the claimed invention. Rather it would result in using the cross-linking reagents taught in Mitra to produce intra-monomer and inter-monomer cross-links.

This is not persuasive because there is nothing in the instant claims that precludes providing intra-monomer or inter-monomer cross-links. The point of Lacroix is to teach three-dimensional modeling of a protein using cross-linking, as is instantly claimed.

3. Applicant states that Havel describes using basic distance geometry to solve for structures which satisfy the geometry. Applicant further argues that Havel does not suggest providing a set of candidate three-dimensional conformations for the protein's primary sequence and then applying physical distance constraint information associated with the cross-linking for the identified cross-link fragments to the candidate three-dimensional conformations.

Art Unit: 1631

This is not persuasive because Havel does teach providing a set of three-dimensional conformations. Havel is also relied upon to teach distant constraints. At page 79, paragraph 2, Havel states that residues can be cross-linked in the laboratory and that the data is capable of imposing significant constraints on the range of possible structures when the number of distances measured is comparable with the number of residues in the chain. Conformations consistent with this information were produced by constraining each residue to lie on the surface of a sphere of radius equal to the crystal structure distance to the center of mass for that residue.

Conclusion

The outstanding rejection under 35 USC 112, 2nd paragraph has been withdrawn in view of the amendments to the claims.

Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 24 is free of the prior art because the prior art does not teach or fairly suggest the algorithm presented.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

Art Unit: 1631

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

March 20, 2006
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
3/20/06